

REMARKS

Claims 1-54 are pending in the present application. Claims 1-3, 5-15, 17-19, and 21-26 are canceled herein without prejudice. Claims 27-54 are withdrawn as being directed to non-elected inventions. Claims 4, 16 and 20 are amended herein for clarity and to more particularly define the invention. In addition, withdrawn claims 27, 31, 35, 39 and 45-49 are amended herein to put them in condition for rejoinder upon allowance of the product claims. New claims 55 and 56 are added herein. Support for these amendments and new claims can be found in the original claims and throughout the specification, as set forth below. No new matter is added by these amendments and new claims and their entry is respectfully requested. In light of the amendments and new claims presented herein and the following remarks, applicants respectfully request reconsideration of the pending application and the allowance of the pending claims to issue.

The issues raised in the Office Action dated April 23, 2007 (hereinafter "the Action") are addressed individually below in the order presented therein.

I. Information Disclosure Statement.

The Action states that the Information Disclosure Statement (IDS) of December 22, 2005 fails to comply with 37 C.F.R. 1.98(a)(2) as particular documents cited therein were not received by the U.S. Patent and Trademark Office (PTO). Action, page 2.

Applicants respectfully submit that the IDS filed on December 22, 2005 was compliant with the provisions of 37 C.F.R. 1.98(a)(2). In support of this assertion, Applicants provide a copy of the return receipt requested postcard acknowledged by the USPTO. The postcard indicates that an IDS, a PTO Form 1449 and 119 cited references (non-U.S. patent or U.S. patent publication references) were included with the submission of December 22, 2005.

Applicants resubmit legible copies of these documents and respectfully request that the Examiner consider these references in view of the foregoing. Should there be any unresolved issues regarding this matter, applicants respectfully request that the Examiner contact the applicants' representative, Alice M. Bonnen, using the contact information provided below.

II. Drawings.

The Action states that the drawings are objected to because Figure 25G shows two separate amino acid sequences yet indicates that both correspond to SEQ ID NO:20. Action, page 3. The Action further requests corrected drawing sheets be submitted. *Id.*

Submitted herewith is an amended drawing sheet for Figure 25G. As amended, Figure 25G recites a single amino acid sequence 921 amino acids in length. Accordingly, Applicants respectfully submit that the objection to the drawings is obviated and respectfully request its withdrawal.

III. Specification.

A. The Action states that the disclosure is objected to because it does not fully comply with 37 C.F.R. 1.821-1.825. Action, page 3. Specifically, the Action requests that SEQ ID NO:20 be corrected to recite a 921 amino acid sequence ending with Thr921. Action, page 4.

Applicants submit herewith a substitute sequence listing in which claim SEQ ID NO:20 is amended as requested in the Action.

B. Additionally, the Action states that the disclosure is objected to because the specification includes a hand-written arithmetical calculation in the bottom margin of page 75 and requests that a replacement page lacking this hand-written text be submitted. Action, page 4.

Applicants submit herewith a replacement page for page 75. Thus, having addressed each of the objections to the disclosure, Applicants respectfully submit that the objections to the disclosure are overcome and respectfully request their withdrawal.

IV. Rejection under 35 U.S.C. § 101.

The Action states that claim 20 stands rejected under 35 U.S.C. § 101 because the claimed invention allegedly is directed to non-statutory subject matter. Action, page 5. The Action further states that amending claim 20 to recite an isolated cell would be remedial. *Id.*

Claim 20 is amended herein to recite an isolated cell comprising the isolated nucleic acid of Claim 4, as suggested in the Action. Accordingly, Applicants respectfully

submit that the rejection of claim 20 is overcome and respectfully request its withdrawal.

V. Rejection under 35 U.S.C. § 112; Enablement and Written Description.

The Action states that claims 1, 3, 4, 10, 11, 16 and 20 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Action, page 5. Further, the Action states that claims 1, 3, 4, 10, 11, 16 and 20 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. *Id.*

Claims 1, 3, 10, 11, and 16 are canceled herein without prejudice. Therefore, the rejections as they pertain to these claims are moot.

Further, Claims 4 and 20 are amended herein. Support for these amendments can be found in the original claims and throughout the specification for example, at least, in claims 3, 10, 11 and 16; in Figure 26; on page 11; lines 19-22; on page 27, lines 19-32; on page 31, lines 17-21; on page 32, lines 12-24; and on page 36, line 7; through page 37, line 1; and on page 113, lines 1-13. Applicants respectfully submit that no new matter is added by these amendments and respectfully request that they be entered.

Accordingly, Applicants have amended the claims of the present application to clarify and further define the nucleotide and polypeptide sequences of the invention and functional fragments thereof. Thus, in view of the amendments presented herein Applicants respectfully submit that claims of the present invention comply with both the written description and enablement requirements and respectfully request withdrawal of the rejection.

VI. Rejection under 35 U.S.C. § 112; Indefiniteness.

The Action further states that claims 1, 3, 4, 10, 11, 16 and 20 stand rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. Action, page 15. Specifically, the Action states that the claims embrace nucleic acids that encode a "functional fragment" of CLR11.3. *Id.* The Action further states that the metes and bounds of "functional fragment" are unclear since the specification allegedly does not disclose what biological activities are normally associated with CLR11.3. *Id.*

Claims 1, 3, 10, and 11 are canceled herein without prejudice. Therefore, the rejection as it pertains to these claims is moot.

As discussed above, claims 4, 16 and 20 have been amended herein to clarify and further define the functional fragments of the nucleotide and polypeptide sequences of the present invention.

Furthermore, contrary to the assertion in the Action, Applicants respectfully submit that the specification discloses CLR11.3 biological activities. For example, see page 28, lines 1-6, wherein it states that CATERPILLER 11.3 is widely expressed and appears to be pro-inflammatory. On page 30, lines 1-9, the specification discusses representative assays for the functional CATERPILLER polypeptides of the present invention and includes NF- κ B and AP-1 reporter assays, evaluation of activation and /or production of NF- κ B/AP-1 by inducers such as TNF α , IL-1 or TLR signaling molecules, evaluation of cytokine expression and/or profiles and the like. Additionally, on page 114, lines 1-14, the specification discusses data indicating that CATERPILLER 11.3 functions as an inhibitory molecule in the inflammatory signaling pathways leading to activation of NF- κ B and that this inhibitory effect may be mediated through interactions between CATERPILLER 11.3 and molecules such as MyD88 and NIK. Other examples of the function and biological activities of the claimed CATERPILLER 11.3 polypeptides can be found on page 46, line 30 through page 47, line 6; on page 47, line 32, through page 48, line 22; on page 51, lines 1-9; on page 74, lines 17-19; and on page 75, line 27-32. As these examples show, the biological activities of CATERPILLER 11.3 are disclosed in the specification of the instant application.

In view of the amendments to claims 4, 16 and 20 and the foregoing discussion, Applicants respectfully submit that one of skill in the art would know what was encompassed by a functional fragment of the present invention. Therefore, Applicants respectfully submit that the rejection of claims 4 and 20 for indefiniteness has been overcome and respectfully request its withdrawal.

VII. Rejection under 35 U.S.C. § 102(b).

The Action states that claims 1, 3, 4, 10, 11, 16 and 20 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Conklin (WO 01/04307).

Claims 1, 3, 10 and 11 are canceled herein without prejudice. Therefore, the rejection as it pertains to these claims is moot.

Claims 4 and 16 are amended herein to recite SEQ ID NOs:17, 18, 19 and/or 20, and to further define the claimed functional fragments thereof, thereby obviating the

rejection of claims 4, 16 and 20 under 35 U.S.C. § 102 in view of Conklin. Accordingly, Applicants respectfully request that the rejection be withdrawn.

VIII. New Claims.

New claims 55 and 56 are added herein. Support for these claims can be found throughout the specification, for example, at least in Figures 27-28, on page 11, line 24 through page 12, line 12; on page 30, lines 1-9; on page 51, lines 1-3; and on page 114, lines 1-13. Thus, no new matter is believed to be added by entry of these new claims. Further, these claims are believed to be free of the pending rejections for the same reasons set forth above explaining why claims 4, 16 and 20 are free of the pending rejections and their entry and allowance is respectfully requested.

In view of the foregoing, the Applicants respectfully submit that this application is in condition for allowance, which action is respectfully requested. Should the Examiner have any remaining concerns, it is requested that the Examiner contact the undersigned attorney at 919-854-1400 to expedite the prosecution of this application to allowance.

The Commissioner is authorized to charge Deposit Account No. 50-0220 in the amount of \$60.00 as the fee for a one-month extension of time (small entity). This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



Alice M. Bonnen
Registration No. 57,154

CERTIFICATE OF EXPRESS MAIL

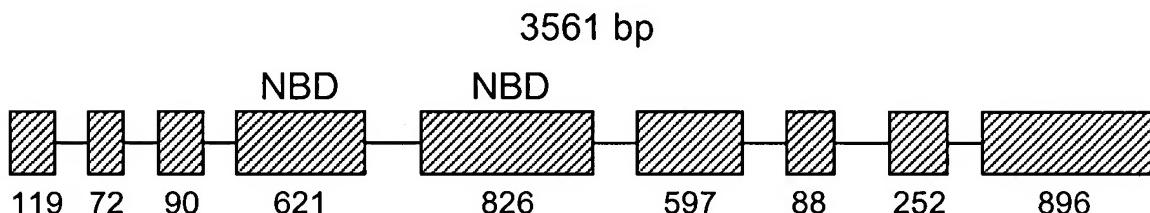
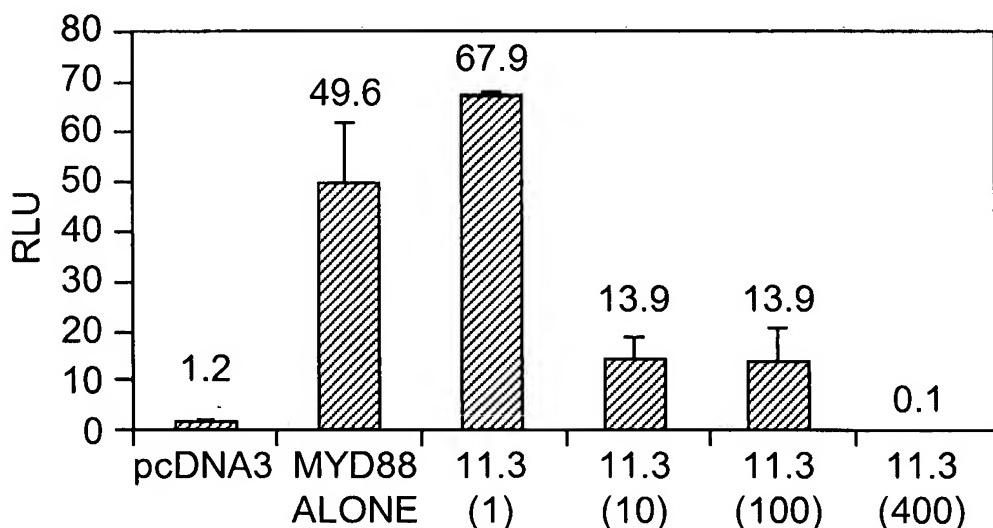
Express Mail Label Number EV 887523889 US
Date of Deposit: August 22, 2007
I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Katie Wu

Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428
Raleigh, North Carolina 27627
Telephone: (919) 854-1400
Facsimile: (919) 854-1401
Customer No. 20792

Enclosures: Computer-readable and paper copy of the Sequence Listing.

1 MRWGHHLPRASWGSGFRRALQRPDDRIPFLIHWWSWPLQGERPFGPPRAFI
 51 RHHGSSVDSAPPGRHGRLFPSASATEAIQRHRRNLAEWFSLRLPREERQF
 101 GPTFALDTVHVDPVIESTPDELLRPPAELALEHQPPQAGLPPPLSQLF
 151 NPDACGRRVQTVVLYGTVGTGKSTLVRKMVLWCYGRLPFELLIPFSCE
 201 DLSSLGPAPASLCQLVAQRYTPLKEVLPLMAAAGSHLLFVLHGLEHLNLD
 251 FRLAGTGLCSDPEEPQEPAAIIVNLLRKYMLPQASILVTTRPSAIGRIPS
 301 KYVGRYGEICGFSDTNLQKLYFQLRLNQPYCGYAVGGSGVSATPAQRDHL
 351 VQMLSRNLEGHHQIAAACFLPSYCWLVCATLHFLHAPTPAGQTLTSIYTS
 401 FLRLNFSGETLDSTDPSNLSLMAYAARTMGKLAYEGVSSRKTYFSEEDVC
 451 GCLEAGIRTEEEFQLLHIFRRDALRFFLAPCVEPGRAGTFVFTVPAMQEY
 501 LAALYIVLGLRKTTLQKVGVKEVAELVGRVGEDVSLVLGIMAKLLPLRALP
 551 LLFNLIKVVPRVFGRMVGKSREAVTQAMVLEMFREEYYNDVDLQMGAS
 601 ILGVEGPRRHPDEPPEDEVFELFPFMGGLSAHNRAVLAQLGCPIKNLD
 651 ALENAQAIKKLGKLGQVLPPSELLDHFFHYEFQNQRFSAEVLSSLRQ
 701 LNLAGVRMTPVKCTVVAAVLGSGRHALDEVNLASCQLDPAGLRTLLPVFL
 751 RARKLGLQLNSLGPEACKDLRDLLLHDQCQITTLRLSNNPLTEAGVAVLM
 801 EGLAGNTSVTHLSLLHTGLGDEGLELLAAQLDRNRQLQELNVAYNGAGDT
 851 AALALARAAREHPSLELLQGVAIQMCWKLPLLPHYAHLWTPRMPHWCFL
 901 ILMPPLPQWYDGLVAPRGRC~~T~~~~LAAIKKPCAFY~~ (SEQ ID NO: 20)

FIG. 25G**FIG. 26**

11.3 TRANSFECTIONS (ng/ml)

FIG. 27
40/68